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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,275	08/24/2001	Christopher P. Adams	EXT-062CN	3814

21323 7590 01/16/2004

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EXAMINER	
CHAKRABARTI, ARUN K	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 01/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

S.A.

Office Action Summary

Application No.	Applicant(s)
09/939,275	Adams
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Dec 15, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-20* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 15, 2003 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1, 5, 7, and 19 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Jiro et al (JP H3[1991]-47097) (February 28, 1991) in view of Gelfi et al (Biotechniques (November 1996) 21:926-32) further in view of Carreira et al. (Analytical Biochemistry, (1980), Vol. 106, pages 455-468).

Jiro et al expressly teaches a method for purifying nucleic acid target molecules from a reaction using a purification device comprising the following steps:

(a) introducing the primer extension sequencing reaction mixture into a purification device comprising an electrophoretic medium, wherein the electrophoretic medium contains immobilized nucleic acid capture probes (Page 6, lines 12-18);

(b) subjecting the electrophoretic medium of step (a) to an electric field resulting in the electrophoretic migration of one, or more, target molecules into at least one region of the electrophoretic medium containing immobilized capture probes, wherein the target molecules bind to immobilized capture probes (Page 6, lines 18-20);

e) collecting the target molecules (Page 6, lines 20-24).

Jiro et al. does not expressly teach the step of imposing conditions on the electrophoretic medium that dissociate the targets and their complementary capture probes.

Gelfi teaches a method of increasing a thermal gradient to cause denaturation of hybridization complexes by increasing the voltage of the gel (abstract and page 926, column 2).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the use of increasing voltage for a separate heating element as taught by Jiro et al. in order to cause denaturation, since Gelfi states "Additionally, the denaturing thermal gradient is not controlled externally, but generated internally by Joule heat produced by voltage ramps (page 926, abstract)". With regard to the use of increased voltage to dissociate the hybridization complex, Jiro et al. expressly teaches the use of increasing temperature to effect the dissociation of the hybridization complex. Jiro et al. uses a separate and external heating source to effect this increased temperature (page 9). Gelfi recognizes Joule's law of electricity which teaches that heat generated in the electrical system is directly proportional to the square of intensity of current which, in turn, is directly proportional to the voltage of the electrical system. Therefore, when Jiro et al. teaches the release of nucleic acids by increasing the temperature, it would have been immediately and prima facie obvious to the ordinary practitioner to substitute the method of Gelfi with the simple use of increasing voltage to increase the temperature of the gel, which serves to minimize the different apparatuses needed to perform the denaturation function, thereby saving material expense, time and effort.

Jiro et al. in view of Gelfi et al do not teach the method of collecting the purified target molecules that have exited the electrophoretic medium.

Carreira et al. teach the method of collecting the purified target molecules that have exited the electrophoretic medium (Abstract and Figure 3).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method of collecting the purified target molecules that have exited the electrophoretic medium as taught by Carreira et al in the method of Jiro et al. in view of Gelfi et al. in order to improve the purification of DNA, since Carreira et al states "The mechanics and methodology described overcome the problem of dilution and losses from excessive manipulations and increases greatly the amount of material which can be processed in a single fraction. In addition, the electronic programming device provides the flexibility in setting collection times so as to maximize resolution for separating samples of varying properties (Page 457, Column 1, line 9 to column 2, line 5)". Therefore, when Carreira et al. teaches the method of collecting the purified target molecules that have exited the electrophoretic medium, it would have been immediately and prima facie obvious to the ordinary practitioner to substitute and combine the method of collecting the purified target molecules that have exited the electrophoretic medium as taught by Carreira et al in the method of Jiro et al. in view of Gelfi et al. in order to achieve the express advantages, as noted by Carreira et al., which overcomes the problem of dilution and losses from excessive manipulations and increases greatly the amount of material which can be processed in a single fraction.

4. Claims 2-4, 10-14, and 16 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Jiro et al (JP H3[1991]-47097) (February 28, 1991) in view of Gelfi et al (Biotechniques (November 1996) 21:926-32) further in view of Carreira et al. (Analytical Biochemistry, (1980),

Vol. 106, pages 455-468) further in view of Cantor et al (U.S. Patent 5,482,836) (January 09,1996).

Jiro et al. in view of Gelfi further in view of Carreira et al. expressly teach the methods of claims 1, 5, 7, and 19 for purifying target molecules as described above.

Jiro et al. in view of Gelfi further in view of Carreira et al. do not teach the method of multiplexing the assay, such as by use of microtiter plates selected from the group consisting of 6, 12, 48, 96, and 384.

Cantor et al. teaches multiplexing the assay by using the microtiter plates which are available in the market as 6 well to 96 well plates as the purification device (Column 7, lines 65-66).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method of multiplexing the assay by using the microtiter plates which are available in the market as 6 well to 96 well plates as the purification device of Cantor et al. in the method of Jiro et al. in view of Gelfi further in view of Carreira et al. since Cantor et al. states, "Another interesting variation of this invention would be multiplexing or using two or more different traps so as to isolate two or more different targets from a single mixture (Column 12, lines 45-47)". An ordinary practitioner would have been motivated to substitute and combine the method of multiplexing the assay by using the microtiter plates which are available in the market as 6 well to 96 well plates as the purification device of Cantor et al. in the method of Jiro et al. in view of Gelfi further in view of Carreira et al. in order

to achieve the express advantages, as noted by Cantor et al., of an invention which provides multiplexing or using two or more different traps so as to isolate two or more different targets from a single mixture.

5. Claims 8, 9, 17, and 18 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Jiro et al (JP H3[1991]-47097) (February 28, 1991) in view of Gelfi et al (Biotechniques (November 1996) 21:926-32)further in view of Carreira et al. (Analytical Biochemistry, (1980), Vol. 106, pages 455-468) further in view of Cantor et al (U.S. Patent 5,482,836) (January 09,1996) further in view of Mullis (U.S. Patent 4683202) (July 28, 1989).

Jiro et al. in view of Gelfi further in view of Carreira et al further in view of Cantor et al expressly teach the methods of claims 1, 5, 7, 19, 2-4, 10-14, and 16 for purifying target molecules as described above.

Jiro et al. in view of Gelfi further in view of Carreira et al. further in view of Cantor et al do not teach the method of extension of primers to form complementary primer extension products which act as templates for synthesizing the desired nucleic acid sequence.

Mullis teaches the method of extension of primers to form complementary primer extension products which act as templates for synthesizing the desired nucleic acid sequence (Column 4, line 15 to Column 15, line 42).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method of extension of primers to form complementary primer extension products which act as templates for synthesizing the desired

nucleic acid sequence of Mullis in the method of Jiro et al. in view of Gelfi further in view of Carreira et al. further in view of Cantor et al. since Mullis states, "The present invention may be useful not only for producing large amounts of an existing nucleic acid or completely specified sequence, but also for producing nucleic acid sequences which are known to exist but are not completely specified (Column 3, lines 19-23)". An ordinary practitioner would have been motivated to substitute and combine the method of extension of primers to form complementary primer extension products which act as templates for synthesizing the desired nucleic acid sequence of Mullis in the method of Jiro et al. in view of Gelfi further in view of Carreira et al. further in view of Cantor et al. in order to achieve the express advantages, as noted by Mullis, of an invention which may be useful not only for producing large amounts of an existing nucleic acid or completely specified sequence, but also for producing nucleic acid sequences which are known to exist but are not completely specified.

6. Claims 6 and 15 are rejected under 35 U.S.C. 103 (a) as being unpatentable over Jiro et al (JP H3[1991]-47097) (February 28, 1991) in view of Gelfi et al (Biotechniques (November 1996) 21:926-32) further in view of Carreira et al. (Analytical Biochemistry, (1980), Vol. 106, pages 455-468) further in view of Stamato et al (U.S. Patent 4,830,726) (May 16, 1989) .

Jiro et al. in view of Gelfi further in view of Carreira et al. expressly teaches the methods of claims 1, 5, 7, and 19 for purifying target molecules as described above.

Jiro et al. in view of Gelfi further in view of Carreira et al. do not teach reversing the polarity of the electric field, wherein the released target molecule will migrate back toward the test sample receptacle and wherein it is subject to collection.

Stamato et al teaches the method of separating DNA molecules by gel electrophoresis which employs alternate applications of high and low strength electric fields in opposite directions to a gel matrix containing DNA (Column 7, line 59 to Column 10, line 13).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the separation of DNA molecules in alternating asymmetric electric fields method of Stamato et al in the purification method of Jiro et al. in view of Gelfi further in view of Carreira et al. since Jiro expressly teaches the "forced movement of DNA fragment sample within the electrophoretic carrier by means of electrophoresis which permits hybridization reaction to take place more rapidly, and the reaction to be completed in shorter time, than would be the case were it to undergo passive diffusion as in the conventional method employing a nitrocellulose membrane. Furthermore, the instant invention permits easy removal, by means of electrophoresis, without employment of washing operations involving filling and discharge solutions and so forth, of the sample that does not bind or binds weakly during the hybridization reaction (Page 11, lines 29-38)." The ordinary practitioner would have combined this concept with that of Stamato, since Stamato et al states with regard to the polarity reversal method that, "one of skill in the art will acknowledge the applicability of this method to DNA from a variety of sources, other compositions appropriate for electrophoretic separation, and for a

variety of known uses of an electrophoretic methods (Column 7, lines 27-32)." An ordinary practitioner would have been motivated to combine the teachings of Jiro et al. in view of Gelfi further in view of Carreira et al. with those of Stamato et al. for the stated and expected benefits of increasing the ability of separating nucleic acid of broad size range as Stamato states, "The advantages offered by the method of the present invention include the ability to separate molecules from about 0.15 to about 2000 Kb (Column 3, lines 20-22)".

7. Claim 20 is rejected under 35 U.S.C. 103 (a) as being unpatentable over Jiro et al (JP H3[1991]-47097) (February 28, 1991) in view of Gelfi et al (Biotechniques (November 1996) 21:926-32) further in view of Carreira et al. (Analytical Biochemistry, (1980), Vol. 106, pages 455-468) further in view of Ghosh et al. (U.S. Patent 5,478,893) (December 26, 1995).

Jiro et al. in view of Gelfi further in view of Carreira et al. expressly teach the methods of claims 1, 5, 7, and 19 for purifying target molecules as described above.

Jiro et al. in view of Gelfi further in view of Carreira et al. do not teach the method wherein the capture probes are immobilized in the electrophoretic medium by copolymerizing the 5'-acrylamide moiety with the electrophoretic medium.

Ghosh et al. teach the method wherein the capture probes are immobilized in the electrophoretic medium by copolymerizing the 5'-acrylamide moiety with the electrophoretic medium (Abstract and Examples 1-6 and claims 1-22).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the method wherein the capture probes are

immobilized in the electrophoretic medium by copolymerizing the 5'-acrylamide moiety with the electrophoretic medium of Ghosh et al in the method of Jiro et al. in view of Gelfi further in view of Carreira et al. since Ghosh et al states, "This results in immobilized oligonucleotides that exhibit superior direct capture ability for complementary oligonucleotides, double stranded DNA, and sandwich hybridization (Column 3, lines 37-40)". An ordinary practitioner would have been motivated to substitute and combine the method wherein the capture probes are immobilized in the electrophoretic medium by copolymerizing the 5'-acrylamide moiety with the electrophoretic medium of Ghosh et al in the method of Jiro et al. in view of Gelfi further in view of Carreira et al. in order to achieve the express advantages, as noted by Ghosh et al., of a method which provides immobilized oligonucleotides that exhibit superior direct capture ability for complementary oligonucleotides, double stranded DNA, and sandwich hybridization.

Response to Arguments

8. Applicant's arguments with respect to all pending claims have been considered but are not persuasive.

In response to applicant's arguments against the references individually (page 2, paragraph 2 to page 4, paragraph 2), one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant also argues (page 2, paragraph 2 and page 3, last paragraph, and page 4, second paragraph) that there is no motivation to combine the references. This argument is not persuasive especially in presence of strong motivation provided by Carreira et al since Carreira et al. states "The mechanics and methodology described overcome the problem of dilution and losses from excessive manipulations and increases greatly the amount of material which can be processed in a single fraction. In addition, the electronic programming device provides the flexibility in setting collection times so as to maximize resolution for separating samples of varying properties (Page 457, Column 1, line 9 to column 2, line 5)". The same logic is applicable to all other combinatory references.

Applicant argues (Page 3, second paragraph) that Jiro et al reference does not teach the dissociation of the nucleic acid hybrids of the claimed invention. Applicant argues that the word "dissociation" was not found in Jiro et al reference. Applicant argues that because Jiro et al has a preferred embodiment of electrophoresis of hybrid nucleic acid molecules at a lower temperature, Jiro et al is limited to the preferred embodiment. This argument is not persuasive. As MPEP 2123 states "Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi,169 USPQ 423 (CCPA 1971)." MPEP 2123 also states " A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories , 10 USPQ2d 1843 (Fed. Cir. 1989)." It is clear that simply because Jiro et al has a preferred embodiment, this embodiment does not prevent the reference from suggesting

broader embodiments in the disclosure and that this does not constitute a teaching away. Although Jiro et al reference uses lower voltage and current to isolate the biomolecules in an electrophoretic medium, the property of isolating a biomolecule by higher temperature is inherently present in each single of this chemically and structurally identical molecule. With regard to the use of increased voltage to dissociate the hybridization complex, Jiro et al. expressly teaches the use of increasing temperature to effect the dissociation of the hybridization complex. Jiro et al. uses a separate and external heating source to effect this increased temperature (page 9). Gelfi recognizes Joule's law of electricity which teaches that heat generated in the electrical system is directly proportional to the square of intensity of current which, in turn, is directly proportional to the voltage of the electrical system. Therefore, when Jiro et al. teaches the release of nucleic acids by increasing the temperature, it would have been immediately and prima facie obvious to the ordinary practitioner to substitute the method of Gelfi with the simple use of increasing voltage to increase the temperature of the gel, which serves to minimize the different apparatuses needed to perform the denaturation function, thereby saving material expense, time and effort. Moreover, MPEP 2111 states, "Claims must be given their broadest reasonable interpretation. During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification". Applicant always has the opportunity to amend the claims during prosecution and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than it is justified. *In re Prater,* 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)". In this case, any

suitable temperature (as suggested by Jiro et al in view of Gelfi et al.) can be used to dissociate hybridized nucleic acids , which are nothing but routine optimization and under any suitable condition can be used to separate a hybridized biomolecule.

In view of the response to argument, 103(a) rejection is hereby maintained properly.

Applicant then argues (page 4, first paragraph) that the 103 rejection is improper because it lacks a reasonable expectation of success.

With regard to the "expectation of success" argument, The MPEP 2143.02 states "Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. In re Rinehart , 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (Claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at superatmospheric pressure were rejected as obvious over a reference which taught the claimed method at atmospheric pressure in view of a reference which taught the claimed process except for the presence of a solvent. The court reversed, finding there was no reasonable expectation that a process combining the prior art steps could be successfully scaled up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully.). See also Amgen, Inc. v. Chugai Pharmaceutical Co ., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir.), cert. denied , 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success. 18 USPQ2d at 1022, 1023.); In re O'Farrell , 853

F.2d 894, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (The court held the claimed method would have been obvious over the prior art relied upon because one reference contained a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, and evidence suggesting the modification would be successful.)."

There is no evidence of record submitted by applicant demonstrating the absence of a reasonable expectation of success. There is evidence in the Jiro et al and Gelfi et al. references of the enabling methodology, the suggestion and scientific reasoning to modify the prior art, and evidence that a number of different voltage rabges were used to denature nucleic acid hybrids as Gelfi et al. states, "Additionally, the denaturing thermal gradient is not controlled externally, but generated internally by Joule heat produced by voltage ramps (page 926, abstract)". Moreover, Carreira et al states "The mechanics and methodology described overcome the problem of dilution and losses from excessive manipulations and increases greatly the amount of material which can be processed in a single fraction. In addition, the electronic programming device provides the flexibility in setting collection times so as to maximize resolution for separating samples of varying properties (Page 457, Column 1, line 9 to column 2, line 5)" This evidence of functionalities trumps the attorney arguments, which argues that all the reference is an invitation to research, since Jiro et al. Gelfi et al and Carreira et al. steps beyond research and shows the functional product.

In view of the response to arguments, all 103(a) rejections have been maintained properly.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti whose telephone number is (571)272-0740. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782 The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group LIE Chantae Dessau whose telephone number is (703) 605-1237.

Arun Kr. Chakrabarti

ARUN K. CHAKRABARTI
PATENT EXAMINER

Arun Chakrabarti,

Patent Examiner

January 5, 2004

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